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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/142,628	06/10/99	MYERS L	1038-833MIS

HM12/0328

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AIR MAIL

EXAMINER	
PAK, M	
ART UNIT	**PAPER NUMBER**
1646	11

DATE MAILED: 03/28/01

AIR MAIL

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/142,628	Myers et al.
Examiner	**Group Art Unit**
Michael Pak	1646

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-25* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-25* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-17, and 25, drawn to a purified and isolated nucleic acid, a vector, a transformed host, a method of forming a substantially pure recombinant transferrin receptor protein, and a diagnostic kit, classified in Class 435, subclass 69.1.

II. Claim 18-21, drawn to a recombinant transferrin receptor, classified in Class 530, subclass 350.

III. Claims 22 and 23, drawn to an immunogenic composition, and a method for generating an immune response, classified in Class 514, subclass 44.

IV. Claims 24, drawn to a method of determining the presence of a nucleic acid, classified in Class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons.

The products of inventions I and II, are distinct each from the other, because they are drawn to products having materially different structures and functions.

The products of inventions I and III, are distinct each from the other, because they are drawn to products having materially different structures and functions or the Group III comprises additional immunogen carrier compounds which are necessary for

the practice of the invention.

The products of inventions I, and the process of invention III or IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the DNA and vector of invention I can be used for producing recombinant proteins.

The transformed host product of inventions I is not used in or produced by any one of the processes of inventions III or IV, and is distinct from each other.

The methods of inventions I, III, and IV, are distinct, each from the other, because they are drawn to processes having materially different process steps, which are practiced for materially different purposes.

The products of inventions II and III, are distinct each from the other, because they are drawn to products having materially different structures and functions or the Group III comprises additional immunogen carrier compounds which are necessary for the practice of the invention.

The process of inventions I, and any one of the products of inventions II or III are related as process of making and product

made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be used to make a materially different process such as by a chemical peptide synthesizer.

The product of inventions II is not used in or produced by the process of invention IV, and is distinct from each other.

The products of inventions II, and the process of invention III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §806.05(h)). In the instant case the protein of invention II can be used for transferrin binding assays.

The products of inventions III and IV, are distinct each from the other, because invention IV contains additional pharmaceutically acceptable carrier product which are necessary for the practice of the invention. Furthermore, the product of invention IV are limited to use in a method of administering the pharmaceutical composition of invention IV, while the product of

invention III may be used for other purposes such as generating antibodies.

The immunogenic composition product of inventions III is not used in or produced by the process of invention IV, and is distinct from each other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their different classifications and recognized divergent subject matter, and the search required for any one of inventions I-IV is not required for any other invention I-IV, restriction for examination purposes as indicated is proper.

In the event Group III is elected, applicants are required to elect as follows:

Claims 22 and 23 are generic to a plurality of disclosed patentably distinct species comprising:

A) a purified and isolated nucleic acid molecule, classified in Class 514, subclass 44;

B) a recombinant transferrin receptor, classified in Class 424, subclass 251.1.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be

obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

These species are distinct for the reasons given above and have acquired a separate status in the art because of their different classifications and recognized divergent subject matter, and the search required for species A is not required for species B; thus, the restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. §1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is

(703) 305-7038. The examiner can normally be reached on Monday through Friday from 5:50 AM to 2:20 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-[illegible].

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Michael P. Pak

Michael Pak
Primary Patent Examiner
Art Unit 1646
20 March 2001